

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INC., BIOGEN SWISS)	
MANUFACTURING GMBH, and)	
ALKERMES PHARMA IRELAND)	
LIMITED,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 23-732 (GBW)
)	
ZYDUS WORLDWIDE DMCC, ZYDUS)	
PHARMACEUTICALS (USA) INC., and)	
ZYDUS LIFESCIENCES LIMITED,)	
)	
Defendants.)	

PROPOSED STIPULATED PROTECTIVE ORDER

WHEREAS, all parties in their business practices have gone to great lengths to safeguard and protect the confidentiality of the documents and information the disclosure of which would pose a substantial risk of irreparable harm to the Producing Party's legitimate proprietary interests;

WHEREAS, discovery in these actions may involve the disclosure of certain documents, things and information in the possession, custody or control of a party or a non-party that constitute or contain trade secrets or other confidential research, development, manufacture, regulatory, financial, marketing or other competitive information within the meaning of Federal Rule of Civil Procedure 26(c)(1)(G);

WHEREAS, the parties have established good cause for entry of this Stipulated Protective Order;

WHEREAS, this Order provides reasonable restrictions on the disclosure of such sensitive materials of a confidential nature;

WHEREAS, all parties agree to the terms of this Order to protect their confidential documents, things and information;

WHEREAS, to streamline the discovery process and minimize the need for Court intervention, this Order adopts an approach that allows the Producing Party to designate certain materials being produced or testimony as CONFIDENTIAL or HIGHLY CONFIDENTIAL. Disclosure of materials designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL is limited to specific classes of persons; and WHEREAS, this Order also provides that the party requesting production of the information may challenge the Producing Party's confidentiality designation before the Court, thereby minimizing the likelihood that non-sensitive documents will be unnecessarily designated as confidential;

THEREFORE, in view of the foregoing and because the parties hereto, by and through their respective counsel have stipulated to the entry of the following Order pursuant to Fed. R. Civ. P. 26(c), and the Court having determined that good cause exists for entry of this Order,

IT IS HEREBY STIPULATED, AGREED, AND ORDERED BY THE COURT as follows:

1. Scope of Protective Order

This Order shall apply to all documents, things and information provided in these actions or in aid of these actions, including, without limitation, all documents or things produced in response to requests for the production of documents and things or subpoenas, answers to interrogatories, responses to requests for admission, testimony adduced at depositions and, upon written questions, all other discovery taken pursuant to the Federal Rules of Civil Procedure or District of Delaware local rules, and any other information furnished, directly or indirectly, by or on behalf of any party to these actions or any non-party. The party(ies) or non-party(ies) producing such information are referred to hereafter as the "Producing Party(ies)" and the party(ies) receiving such information are referred to hereafter as the "Receiving Party(ies)."

2. Definitions

The terms “CONFIDENTIAL,” “CONFIDENTIAL INFORMATION,” “HIGHLY CONFIDENTIAL,” and “HIGHLY CONFIDENTIAL INFORMATION,” as used herein, are defined as follows:

- (a) “CONFIDENTIAL” and “CONFIDENTIAL INFORMATION” mean any form of confidential research, development, manufacture, regulatory, financial, marketing, commercial information, personnel information that is non-public, or other competitive information within the meaning of Fed. R. Civ. P. 26(c)(1)(G). The designation of “CONFIDENTIAL” or “CONFIDENTIAL INFORMATION” by a Producing Party constitutes its representation that it reasonably and in good faith believes that the designated material constitutes or contains information in one or more of the foregoing categories within the meaning of Fed. R. Civ. P. 26(c)(1)(G). Information shall be designated CONFIDENTIAL or CONFIDENTIAL INFORMATION if it constitutes, contains, or otherwise references (i) any abbreviated new drug application that purports to cover any diroximel fumarate product (“diroximel fumarate ANDA”); (ii) new drug application 211855 (“Vumerity[®] NDA”); (iii) any correspondence with the FDA regarding any diroximel fumarate ANDA or Vumerity[®] NDA; (iv) drafts of items (i), (ii), or (iii) above; (v) drug master files (“DMFs”) related to any diroximel fumarate ANDA or Vumerity[®] NDA; (vi) sensitive and/or proprietary historical financial or commercial information, including information pertaining to marketing, sales, revenues, or profits; and (vii) scientific or technical information relating to the research and development of any diroximel fumarate product, whether or not

related to the preparation and filing of a diroximel fumarate ANDA or Vumerity® NDA.

- (b) “HIGHLY CONFIDENTIAL” and “HIGHLY CONFIDENTIAL INFORMATION” mean information that constitutes, contains, or otherwise references trade secrets (including any contained within the Vumerity® NDA or diroximel fumarate ANDA), unpublished pending patent applications, abandoned patent applications, draft patent applications, or proposed patent applications, whether foreign or domestic, pending NDAs, pending ANDAs, products in development or not commercially launched, competitive forward-looking financial or strategic commercial information, including forecasts and financial assumptions, the disclosure of which to another party or third party could cause a competitive disadvantage to a Producing Party or could create a substantial risk of serious harm that could not be avoided by less restrictive means. For clarity, any information, item, or tangible thing enumerated in ¶ 2(a) that also meets the requirements of ¶ 2(b) may be designated as HIGHLY CONFIDENTIAL.

The term “In-House Legal Representative(s)” shall mean (a) attorneys or persons responsible for overseeing and making decisions related to intellectual property litigation, who are (b) employees of a Party or its subsidiary, parent, affiliate, and/or licensee who do not and shall not have direct responsibility for, and shall not directly or indirectly provide any information in connection with, prosecuting or filing any patent applications claiming pharmaceutical compounds or compositions containing diroximel fumarate, including but not limited to methods of using, manufacturing, or processing thereof, and (c) do not and shall not have direct responsibility for submitting regulatory documents to FDA or for communications with FDA involving diroximel

fumarate (with the exception of involvement in the preparation and filing of certifications pursuant to 21 U.S.C. § 355(b)(2)(A)(i)-(iv) and 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV) and (viii) and notices pursuant to 21 U.S.C. § 355(j)(2)(B)), including without limitation any Citizen Petition, for the pendency of this litigation and for a period of one year after final termination of this litigation, including appeals.

3. Non-Parties under the Order

If a third party provides discovery to any party in the above-captioned cases, such third party may adopt the terms of this Order with regard to the production of CONFIDENTIAL INFORMATION and HIGHLY CONFIDENTIAL INFORMATION by executing and filing with the Court a Notice of Election to Adopt Stipulated Protective Order (“Notice of Election”) in the form attached hereto as Exhibit B. In the event of such election, the provisions of this Order shall apply to any information provided by the non-party in discovery in these actions, and the non-party shall have the same rights and obligations under this Order as held by the parties to these actions, and the parties will treat such information in accordance with this Order.

4. Discovery of Non-Party Information

A Producing Party may redact the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION of a non-party that is in its possession where the Producing Party is under an obligation not to disclose such information.

5. Marking Documents and Things

If a document or thing constitutes or contains CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, every page of that document or that thing shall be labeled or marked with the legend “CONFIDENTIAL” or “CONFIDENTIAL INFORMATION” or “HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY” or “HIGHLY CONFIDENTIAL INFORMATION – OUTSIDE COUNSEL ONLY,” respectively, when the

document or thing is produced to the Receiving Party. Anything that cannot be so labeled or marked on its face shall be labeled or marked by placing the appropriate legend on a container or package in which it is produced or on a tag attached thereto. Material produced without any such legend shall not be subject to the protections afforded such information under this Order unless otherwise agreed to by the Parties, ordered by the Court or designated in accordance with Paragraph 9 of this Order.

Inspection by a Receiving Party of a Producing Party's materials prior to production shall be conducted only by persons eligible under Paragraph 13 below. Such persons shall initially treat all materials disclosed during inspection as containing HIGHLY CONFIDENTIAL INFORMATION until such materials are produced. Thereafter, such materials shall be treated by the Receiving Party in accordance with the confidentiality designation made at the time of their production.

With respect to all original documents that are made available for inspection, designation by stamping as "CONFIDENTIAL" or "CONFIDENTIAL INFORMATION" or "HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY" or "HIGHLY CONFIDENTIAL INFORMATION – OUTSIDE COUNSEL ONLY" need not be made until copies of the materials are requested after inspection and selection by counsel. Making documents available for inspection shall not constitute a waiver of any claim of confidentiality or any applicable privilege or immunity and all materials made available for inspection shall be treated as if designated as HIGHLY CONFIDENTIAL INFORMATION pursuant to this Order.

6. Marking Interrogatories, Requests for Admissions and Deposition Testimony on Written Questions

If a response to interrogatories, response to requests for admissions or deposition testimony upon written questions constitutes or contains CONFIDENTIAL INFORMATION or HIGHLY

CONFIDENTIAL INFORMATION, every page thereof shall be labeled or marked with the legend “CONFIDENTIAL” or “CONFIDENTIAL INFORMATION” or “HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY” or “HIGHLY CONFIDENTIAL INFORMATION – OUTSIDE COUNSEL ONLY,” respectively, when the response or testimony is served upon the Receiving Party. Such responses or testimony served without any such legend shall not be subject to the protections afforded such information under this Order unless otherwise agreed to by the parties, ordered by the Court, or designated in accordance with Paragraphs 7 and 9 of this Order. Notwithstanding the foregoing, if a party marks only the cover page of a response to interrogatories, response to requests for admissions, or deposition testimony upon written questions as constituting or containing CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION and erroneously fails to mark every other page of that item, the Receiving Party shall not disclose any part of that item until clarifying the designation issue with the Producing Party.

7. Marking Deposition Testimony

Any portion of a deposition may be designated CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION during the deposition itself. Regardless of whether such a designation is made during the deposition, all testimony adduced at depositions and any transcripts thereof will be presumptively treated as HIGHLY CONFIDENTIAL INFORMATION for a grace period beginning from the date of the deposition until thirty (30) days after a complete copy of the transcript has been provided to the deponent or the deponent’s counsel. Within this thirty-day grace period, any party may designate any additional portion of any deposition transcript as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION by specifying in writing the portion of the transcript believed to constitute or contain CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION by page

and line number. If no such designation is made during a deposition or the thirty-day grace period, the transcript from such deposition shall not be subject to the protections afforded such information under this Order unless otherwise agreed to by the Parties, ordered by the Court or designated in accordance with Paragraph 9 of this Order.

8. Limitations on Attendance at Depositions

Counsel for a Producing Party may request that all persons other than the witness, the court reporter, those individuals specified in Paragraphs 12 or 13, and counsel for the witness (if a non-party witness) leave the deposition room during any portion of a deposition that inquires about or discloses subject matter that such counsel deems CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION. For avoidance of doubt, counsel for a Producing Party may request that all In-House Legal Personnel specified in Paragraph 12 leave the deposition room during any portion of a deposition that inquires about or discloses subject matter that such counsel deems HIGHLY CONFIDENTIAL INFORMATION. If such individuals fail to comply with such a request, the requesting counsel for the Producing Party may seek relief from the appropriate Court and, pending resolution of that request, instruct or request the witness not to answer questions relating to, or to limit disclosure of, the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION at issue.

9. Inadvertent Production of CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION

If a Producing Party inadvertently or mistakenly produces any CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION without labeling, marking or designating it as provided in this Order, the Producing Party may, within fourteen (14) days after learning of the inadvertent or mistaken production, give written notice to the Receiving Party that the material at issue is or contains CONFIDENTIAL INFORMATION or HIGHLY

CONFIDENTIAL INFORMATION and should be treated as such in accordance with this Order. In such instance, the Producing Party shall also provide copies of the material at issue properly marked as required under this Order. Upon receipt of such notice and properly marked material, the Receiving Party shall treat such information consistent with the re-designation. Disclosure of such information to persons not authorized to receive CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION prior to receipt of such notice shall not be deemed a violation of this Order, except as provided for above.

Should any CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION be disclosed, through inadvertence or otherwise, by the Receiving Party to any person or party not authorized under this Order, then the Receiving Party shall (a) use its best efforts to obtain the return of any such material or information and to bind such person to the terms of this Order; (b) within five (5) days of the discovery of such disclosure, inform such person of all provisions of this Order and request such person to sign the Undertaking to be Bound in the form attached hereto as Exhibit A; and (c) within seven (7) days of the discovery of such disclosure, inform the Producing Party of all pertinent facts relating to such disclosure, including the identity of such person and the information disclosed. Compliance with the foregoing shall not prevent the Producing Party from seeking further relief from the Court.

10. Inadvertent Production of Privileged or Work Product Information

If a Producing Party inadvertently or mistakenly produces or fails to redact any hard copy, electronic or other material information that it believes should have been withheld subject to a claim of attorney-client privilege, work product immunity or other privilege or immunity, such inadvertent or mistaken production shall in no way prejudice or otherwise constitute a waiver of or estoppel as to any claim of privilege, work-product immunity or other privilege or immunity with respect to such information. In such an event, the Producing Party shall request in writing

within fourteen (14) days of learning of such inadvertent or mistaken production the return of the material for which a claim of inadvertent or mistaken production is made. Upon receiving notice of inadvertent production, the Receiving Party shall not make any use of such document or thing or disseminate same in any way. Within fourteen (14) days of receiving such a written request from the Producing Party, the Receiving Party shall return to the Producing Party the material that the Producing Party represents is covered by a claim of attorney-client privilege, work-product immunity or other privilege or immunity and was inadvertently or mistakenly produced, and the Receiving Party shall destroy all copies and notes or summaries relating thereto.

Notwithstanding the above, recognizing the parties' need to prepare their cases based on the discovery that is produced, if any material is used in a court hearing, in a deposition, as an exhibit to a motion or referenced in an expert report, brief, memorandum or pretrial order, or is otherwise used openly in the above-referenced cases, any claim of inadvertent production must be made within fourteen (14) days after such use.

If the Receiving Party wishes to contest that any such document or thing is protected by the attorney-client privilege or by work-product immunity, the Receiving Party shall so notify the Producing Party in writing when the document or thing is destroyed or returned to the Producing Party ("Notice of Challenge"). Return of the discovery by the Receiving Party shall not constitute an admission or concession, or permit any inference, that the returned document or thing is, in fact, properly subject to a claim of privilege, work product immunity, or other protection from disclosure, nor shall it foreclose any party from moving the Court (in accordance with the Court's procedures for resolution of discovery disputes) for an order that such document or thing has been improperly designated or should be discoverable and usable in this action for reasons other than a waiver caused by the inadvertent production or providing of discovery. If such a

motion is made, the burden of proof to show that a document or thing has been improperly designated or should be discoverable and usable shall be on the Receiving Party, who shall not rely on any portion of the document other than the information contained in a Privilege Log provided by the Producing Party in or as otherwise agreed-to by the parties or ordered by the Court.

Within five (5) business days after receiving a Notice of Challenge, the Producing Party shall provide to the Receiving Party for each such document or thing a description of the basis for the claim of privilege or immunity.

Within five (5) business days after receiving such description, the Receiving Party shall seek relief from the Court to compel production of such documents and things, the protection of which is still disputed, in accordance with the Court's procedures for resolution of discovery disputes, or the issue is deemed waived.

With respect to documents and things subsequently generated by a Receiving Party, which documents and things contain information derived from such inadvertently produced documents and things, if the Receiving Party does not notify the Producing Party that the Receiving Party disputes the claims of attorney-client privilege or work-product immunity, or if the Court rejects any challenge by the Receiving Party to the privileged status of the inadvertent production, the Receiving Party shall either destroy the derivative documents and things or redact from them all such derivative privileged or work-product information in a manner such that the derivative information cannot in any way be retrieved or reproduced (with the exception of derivative information stored on back-up tapes or other archival media, which should be treated in accordance with standard retention policies, i.e., which are not retained indefinitely without being overwritten and are not accessible).

The procedures set forth in this ¶ 10 for challenging the privileged status of an inadvertent production shall not result in any waiver of the attorney-client privilege, the work product immunity, or any other privilege or immunity.

The facts or circumstances of the inadvertent production shall in no way be relied upon as a ground to support any argument that the information is no longer subject to any applicable privilege or immunity. For purposes of this section, it shall be irrelevant which party initially discovers the inadvertently or mistakenly produced items that are otherwise properly subject to a claim of attorney-client privilege, work product immunity, or on any other protection from discovery.

For purposes of ¶ 10, any disclosure of information that a party claims is privileged or subject to work product protections shall be deemed to be inadvertent.

11. Disclosure and Use of Designated Materials

Subject to the limitations and restrictions of this Order and any further order of the Court, material designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION may be used in testimony at trial, offered into evidence at trial and/or other hearings and proceedings, including in the pre-trial phase of these actions, and used to prepare for and conduct discovery, to prepare for trial and to support or oppose any motion in these actions. The parties agree to meet and confer in good faith prior to trial to attempt to agree on procedures concerning the use of CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION at trial, consistent with the then-governing law regarding public access to trials. Nothing in this Protective Order shall preclude any party from moving the Court to seal the courtroom, trial exhibits, or the trial transcript in order to preserve the confidential nature of any CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION used at trial. Subject to any further order regarding confidentiality as this Court may enter, a Producing

Party may request that any person not permitted access to CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION under Paragraph 12 or 13 be barred from attending any portion of trial or any other hearing at which CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION is or will be revealed.

Material designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, and all information derived therefrom, shall be used only by persons permitted access to such information under this Order, shall not be disclosed by the Receiving Party to any party or person not entitled under this Order to have access to such material and shall not be used by the Receiving Party for any purpose other than in connection with these actions, including without limitation for any research, development, manufacture, patent prosecution, financial, commercial, marketing, regulatory, business or other competitive purpose, or in any communication, argument or statement to the FDA. Absent consent of the Producing Party and/or further order of this Court, all persons receiving information designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION are expressly prohibited from using or disclosing such information in connection with any practice before, or communication with, the United States Patent and Trademark Office (“USPTO”), the FDA, the United States Pharmacopoeia, or their counterpart organizations in any foreign jurisdiction.

In addition, any person who receives or reviews CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION produced by any party other than his or her client shall not thereafter, during the pendency of the instant litigation and for one year after the final conclusion of this litigation, including appeals:

- (i) amend, draft, or otherwise substantively assist in the drafting or amending of patent claims in any patent prosecution, reissue, reexamination, post-grant review (“PGR”), inter partes review (“IPR”), or similar foreign proceeding, claiming pharmaceutical compounds or compositions containing diroximel fumarate, including but not limited to methods of using, manufacturing, or processing thereof. For the avoidance of doubt, the prior sentence does not prohibit attorneys, agents, or legal representatives receiving CONFIDENTIAL or HIGHLY CONFIDENTIAL INFORMATION from participating in PGRs or IPRs, or similar foreign proceedings, including oppositions, so long as those attorneys, agents, or legal representatives receiving CONFIDENTIAL or HIGHLY CONFIDENTIAL INFORMATION do not amend, draft, or otherwise substantively assist in the drafting or amending of patent claims in such proceedings.
- (ii) participate in or aid in the filing of any FDA Citizen Petition related to diroximel fumarate.
- (iii) The foregoing restrictions of this Paragraph shall apply only to individuals, and not to the firms or organizations by which they are employed, nor to individuals who received access to CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION solely in their capacity as clerical staff.

12. Access to CONFIDENTIAL INFORMATION

CONFIDENTIAL INFORMATION of another party as described in this Order may only be disclosed to:

- (a) Litigation counsel of record for the parties and their partners, associates, data entry, information processing, computer support, litigation support, translating, stenographic, clerical and paralegal employees or agents whose duties and responsibilities require access to material designated as CONFIDENTIAL INFORMATION in conjunction with these actions;
- (b) Up to three (3) In-House Legal Representatives for each Plaintiff Group¹, and their stenographic, clerical and paralegal employees whose duties and responsibilities require access to material designated as CONFIDENTIAL INFORMATION. The In-House Legal Representatives for the Plaintiff Groups are those listed below;

Name	Job Title
Jenny Shmuel – Biogen	Litigation Counsel
Martha Born – Biogen	Chief Litigation Counsel
John Kirkland – Alkermes	Intellectual Property and Litigation Counsel

- (c) Up to three (3) In-House Legal Representatives for Defendants, and their stenographic, clerical and paralegal employees whose duties and responsibilities require access to material designated as CONFIDENTIAL INFORMATION. The three In-House Legal Representatives for Defendants shall be provided to Plaintiffs via separate letter at any time prior to the In-House Legal Representatives accessing any of Plaintiffs' information marked CONFIDENTIAL, as permitted herein;

¹ There are two Plaintiff Groups: (1) Biogen Inc. or Biogen Swiss Manufacturing GmbH ("Biogen"); and Alkermes Pharma Ireland Limited ("Alkermes").

- (d) Outside consultants, advisors or experts regarding any issue in these actions who are not current or past employees of any of the parties to these actions or any divisions, subsidiaries, parents, or affiliates of any of the parties to these actions, whose advice and consultation are being or will be used in connection with these actions, including their stenographic and clerical personnel;
- (e) The Court before which these actions are pending and its authorized staff, and court reporters;
- (f) Any interpreter or translation service, and any typist or transcriber used thereby;
- (g) A party's outside vendors (persons or entities) and their staffs that provide litigation support services specifically to assist outside counsel of record with, e.g., copying, exhibit preparation, computerized litigation support, information management service, e-discovery and managed review, graphic design and animation, jury consulting, and mock trial coordination;
- (h) Court reporters, videographers, and their respective staffs employed in connection with these actions; and
- (i) The author(s) or prior recipient(s) of a document containing CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION provided it is established in the document or by agreement of the parties that the person is an author or prior recipient of the document. The CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION that is disclosed, given, shown, made available or communicated to persons pursuant to this subparagraph is limited to the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL

INFORMATION that is contained in the document in which that person has been identified as an author or prior recipient.

Prior to the disclosure of CONFIDENTIAL INFORMATION to any of the persons described in subparagraph (d), counsel for the Receiving Party shall first obtain from each such person a signed Undertaking substantially in the form annexed as Exhibit A. CONFIDENTIAL INFORMATION shall not be disclosed to any outside consultant or expert under subparagraph (d) for a period of seven (7) calendar days after serving the Producing Party with such Undertaking and (i) an up-to-date curriculum vitae or resume (including a list of publications and employment history) for any such consultant or expert, (ii) the identification of any prior or current relationship with any party to the actions, and (iii) a list of the cases in which the consultant or expert has testified at deposition, at a hearing, or at trial within the last four (4) years.

Service of the Undertaking shall be made by e-mail. The parties may agree in writing to shorten the waiting period for disclosure of confidential information.

Counsel for the Producing Party may within seven (7) days after service of the Undertaking serve a written objection if a reasonable basis for such objection exists. The objection shall state with particularity the basis for the objection. CONFIDENTIAL INFORMATION will not be disclosed to the person as to whom the objection was served, absent agreement by the Producing Party who served the objection. If no such agreement is reached within seven (7) days after service of the objection, counsel for the Producing Party who served the objection may move the Court for an order denying disclosure of any CONFIDENTIAL INFORMATION to the person as to whom the objection was served. On such proceedings, the Producing Party shall have the burden of proving why the Court should deny the disclosure of CONFIDENTIAL INFORMATION. If the Producing Party files such a motion, CONFIDENTIAL INFORMATION shall not be disclosed

to the person as to whom the objection was served until the Court rules or agreement is reached that such disclosure may be made. Failure to file such a motion within fourteen (14) days after the Producing Party's service of the objection on the Receiving Party shall operate as a waiver of such objection.

Any vendor described in Paragraph 12(f), 12(g), or 12(h) who is accessing CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION on behalf of a party shall return to the party's counsel all copies of such documents as soon as the information has been encoded and loaded into the computer, copied, prepared or otherwise processed by the vendor. Any vendor providing a party with ongoing access to CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION shall provide limited and secure access to the information (such as information stored on a computer) and the vendor will guarantee to provide access (e.g., through access codes or passwords) only to people who are entitled to access it under this Order (including people retained or employed by the vendor entitled to such access).

Counsel and all other persons to whom CONFIDENTIAL INFORMATION and HIGHLY CONFIDENTIAL INFORMATION is disclosed pursuant to this Order are responsible for employing reasonable measures to control access to and distribution of documents designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION and shall take reasonable and appropriate precautions to avoid inadvertent disclosure of the CONFIDENTIAL or HIGHLY CONFIDENTIAL INFORMATION.

13. Access to HIGHLY CONFIDENTIAL INFORMATION

HIGHLY CONFIDENTIAL INFORMATION is fully subject to the requirements and limitations set forth in Paragraph 12 regarding the disclosure of CONFIDENTIAL INFORMATION, but shall be disclosed by the Receiving Party only to the individuals falling within subparagraphs (a), (d), (e), (f), (g) (h), and (i) of Paragraph 12.

For the avoidance of doubt, nothing in this Paragraph 13 prohibits or varies the provisions described in Paragraph 18.

14. Disclosure of CONFIDENTIAL INFORMATION and HIGHLY CONFIDENTIAL INFORMATION to Other Individuals

CONFIDENTIAL INFORMATION and HIGHLY CONFIDENTIAL INFORMATION may be disclosed also to persons not identified in Paragraphs 12 and 13 as follows:

- (a) CONFIDENTIAL INFORMATION and HIGHLY CONFIDENTIAL INFORMATION may be disclosed to persons not identified in Paragraphs 12 and 13 as agreed by the Producing Party;
- (b) Any Receiving Party may move the Court for an Order that a person not identified in Paragraphs 12 or 13 be given access to information designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION. If the motion is granted, such person may have access to the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION after first signing an Undertaking substantially in the form of Exhibit A attached hereto.
- (c) CONFIDENTIAL INFORMATION and HIGHLY CONFIDENTIAL INFORMATION of a Producing Party may be disclosed to and/or used to examine at deposition, at trial, or at any other court hearing: (i) an individual who is an author or prior recipient of the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, as demonstrated by the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION itself or by agreement of the parties; (ii) if the attorney disclosing such CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION has a good-

faith reasonable belief based upon witness testimony that the witness had knowledge of the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION; (iii) a currently employed officer, employee or expert of a Producing Party; and/or (iv) any outside consultant or expert permitted access to CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION pursuant to Paragraph 12.

- (d) A party may disclose or use in any manner or for any purpose any information or documents from that party's own files that the party itself has designated CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION. Such disclosure shall not waive any of the protections of this Protective Order.

Defendants shall not use any CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION provided by one Plaintiff Group during a deposition of a fact witness of another Plaintiff Group who has not previously had access to the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION of the Plaintiff Group whose CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION is being used. The parties agree to meet and confer in good faith prior to trial to attempt to agree on procedures concerning the use of CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION provided by one Plaintiff group during a cross-examination of a fact witness of another Plaintiff Group who has not previously had access to the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION of the Plaintiff Group whose CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION is being used.

15. Request for Production in Another Action

If any Receiving Party (a) is subpoenaed or served with a demand in an action not subject to this Order, or (b) is served with any legal process by one not a party to these actions, seeking any material designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, such Receiving Party shall object to its production to the extent permitted by law and shall give prompt written notice to the Producing Party. Should the person seeking access to material designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION take action against such Receiving Party or anyone else covered by this Order to enforce such a subpoena, demand, or other legal process, such Receiving Party shall respond by setting forth the existence of this Order and provide prompt written notice to the Producing Party.

By entering this Order and limiting the disclosure of information in these cases, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this Order who becomes subject to a motion to disclose another party's information designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION pursuant to this Order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

16. Filing Under Seal

If any party files CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION (including confidential portions of documents or transcripts) or any document, pleading or brief that discloses the substance or content of CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION in connection with any motion, other written submission, hearing or trial in these actions, the filing party shall make such filing under seal; provided, however, that the burden of proving that such information should be sealed shall at all

times remain with the party which designated the information as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION.

If a party wishes to file CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION with the Court, it shall take reasonable steps to ensure that such information is impounded, kept under seal, and unavailable to the public, in accordance with the applicable Federal Rules of Civil Procedure, the District of Delaware local rules and the Court's Administrative Procedures Governing Filing and Service by Electronic Means ("CM/ECF Procedures"). Any party filing CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION shall comply with the local rules of the Court and procedures of the Clerk's office for sealed filing, and shall ensure delivery of all sealed filings to all counsel of record via electronic means, for example via email, or other electronic procedures agreed by the parties (such as FTP transfer, etc.).

17. Challenging Designations

The acceptance by the Receiving Party of material designated CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION shall not constitute an admission or concession, or permit an inference that such material is, in fact, confidential. Any Receiving Party may at any time request that the Producing Party cancel or modify a CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION designation. Such request shall be made to counsel for the Producing Party in writing and shall particularly identify the designated CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION that the Receiving Party contends is not CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION and the reasons supporting that contention. If the Producing Party does not agree to remove or modify the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION designation within seven (7)

days of such request, and the dispute cannot be resolved in good faith, the party contending that such documents or material are not properly designated may, after making a reasonable effort to reach agreement pursuant to D. Del. LR 7.1.1, request that the Court change the designation or remove such material from any or all of the restrictions of this Order. On such proceedings, the objecting party challenging the confidentiality designation shall have the burden of proving that the material designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION does not warrant the applicable protections under this Order.

All documents and other materials designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION shall be treated as such, under the terms of this Order, unless and until such designation is revoked by the designating party or the Court.

18. Limitations on Advice to Clients

Nothing in this Order shall bar or otherwise restrict any attorney from rendering advice to its client, and in the course thereof, relying upon such attorney's examination of CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION; provided, however, that in rendering such advice and in otherwise communicating with such client the attorney shall not disclose any CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION to unauthorized persons.

19. Discoverability of Expert Materials

Discovery of communications between counsel and any testifying expert or consultant retained or specially employed by that counsel for purposes of this litigation shall be limited to the factual information, analyses, documents, and/or data relied on by the expert in forming the opinions expressed in an expert report or at trial. Except as otherwise provided herein, all communications between counsel and the expert relating to the process of preparing an expert report or developing opinions for trial, including all preliminary or draft reports, expert working

papers, notes, and communications relating thereto, shall be deemed exempt from discovery and use at trial. Non-testifying experts shall not be subject to discovery unless a testifying expert is relying on the opinions formed by or work performed by such non-testifying experts.

20. No Expansion of Federal Rules of Civil Procedure

Nothing in this Order shall be construed to (a) affect or govern the scope of discovery in these actions, (b) preclude any party from moving the Court for a further order of additional protection, modifications of the terms of this Order or to relax or rescind the restrictions of this Order pursuant to Fed. R. Civ. P. 26(c) or any other provision of the Federal Rules of Civil Procedure, (c) require a party to produce any CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION that is not relevant and discoverable pursuant to Fed. R. Civ. P. 26 and the surrounding case law, (d) preclude any party from moving the Court for an order compelling production or disclosure of such material, (e) require production or disclosure of any CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION protected from disclosure by the attorney-client privilege, the attorney work-product immunity or other privilege or immunity so long as the withheld materials are identified in the manner required by the Federal Rules of Civil Procedure.

21. Survival of Obligations under Protective Order

This Protective Order shall survive the final termination of these actions, including all appeals, and continue to bind all persons to whom CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION is disclosed hereunder to the extent such material is not, or does not become, known to the public. Upon final termination of these actions, including all appeals, outside counsel may retain any archive copies of any filings, court papers, correspondence (including e-mail correspondence), deposition and trial transcripts, deposition and trial exhibits, expert reports, written discovery responses, and attorney work product (regardless

of whether such materials contain or reference CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION) for archival records. All other copies of material designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION (including without limitation all deposition transcripts, production documents and any other summaries, abstracts, excerpts, indices and descriptions of such material, and information derived from such material) shall be within ninety (90) days after the conclusion of this action: (a) assembled and returned (except for any that may be retained by the Court) to the Producing Party; or, alternatively, (ii) destroyed by the Receiving Party. As to other copies of material designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION stored in computer databases, the Receiving Party shall delete all such information and provide notice of such to the Producing Party (except that a party is not obligated to return or destroy such information that may be contained in electronic back-up tapes or disks, which should be treated in accordance with standard retention policies).

As to CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION stored in computer databases or backup tapes or disks located, stored or accessible by any persons other than outside counsel for the Receiving Party, the Receiving Party shall, within ninety (90) days of the final termination of these actions, including all appeals, destroy any media on which CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION was electronically stored at any time, or otherwise take all steps necessary to irretrievably remove such information from any and all such media.

22. Publicly Available Information

The restrictions and obligations set forth herein relating to material designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION shall not apply to any information that (a) the Producing Party agrees or the Court rules should not be

designated as such, (b) is or has become public knowledge other than as a result of disclosure by any Receiving Party, its employees or agents in violation of this Order, or (c) has come or shall come into the Receiving Party's legitimate knowledge or possession independently of the Producing Party under conditions such that its use and/or public disclosure by the Receiving Party would not violate any obligation to the Producing Party. The restrictions and obligations set forth herein shall not prohibit discussions of any material designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION with any person who already has or obtains legitimate possession thereof.

23. Modifications to the Protective Order

This Protective Order may be modified by written stipulation of the parties without further Order of the Court.

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/s/ *Jeremy A. Tigan*

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March 7, 2024

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*Attorneys for Defendants Zydus Worldwide
DMCC, Zydus Pharmaceuticals (USA) Inc.,
and Zydus Lifesciences Limited*

SO ORDERED, this _____ day of _____, 2024.

THE HONORABLE GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE
DISTRICT OF DELAWARE

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INC., BIOGEN SWISS)	
MANUFACTURING GMBH, and)	
ALKERMES PHARMA IRELAND)	
LIMITED,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 23-732 (GBW)
)	
ZYDUS WORLDWIDE DMCC, ZYDUS)	
PHARMACEUTICALS (USA) INC., and)	
ZYDUS LIFESCIENCES LIMITED,)	
)	
Defendants.)	

**DECLARATION AND UNDERTAKING TO BE BOUND
BY COURT ORDER GOVERNING CONFIDENTIALITY OF INFORMATION**

UNDERTAKING OF _____

I, _____, declare under penalty of perjury that:

1. My present address is _____.
2. My present employer is _____ and the
address of my present employer is _____.
3. My present occupation is _____.
4. A copy of my curriculum vitae or resume is attached hereto.
5. I have received a copy of the Protective Order in these actions. I have carefully read
and understand the provisions of the Protective Order.
6. I will comply with all the provisions of the Protective Order and hereby submit to
the jurisdiction of the United States District Court for the District of Delaware for the purposes of
enforcement of the Protective Order in these actions. I will hold in confidence, will not disclose to
anyone not qualified under the Protective Order, and will use only for purposes of these actions

any CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, including the substance and any copy, summary, abstract, excerpt, index or description of such material that is disclosed to me as well as any knowledge or information derived from any of the above-mentioned items.

7. I will return all CONFIDENTIAL INFORMATION and HIGHLY CONFIDENTIAL INFORMATION that comes into my possession and all documents and things that I have prepared relating thereto to counsel for the party by whom I am employed or retained or from whom I received such material, when requested to do so. I acknowledge that return of such materials shall not relieve me from any of the continuing obligations imposed upon me by the Protective Order.

8. I understand that if I violate any provision of the Protective Order, I may be subject to sanctions by the Court, and that the Parties, or any of them may seek other remedies against me. I hereby submit to the jurisdiction of the Court for enforcement of the Protective Order in these actions.

Dated: _____

Signature

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INC., BIOGEN SWISS)	
MANUFACTURING GMBH, and)	
ALKERMES PHARMA IRELAND)	
LIMITED,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 23-732 (GBW)
)	
ZYDUS WORLDWIDE DMCC, ZYDUS)	
PHARMACEUTICALS (USA) INC., and)	
ZYDUS LIFESCIENCES LIMITED,)	
)	
Defendants.)	

NOTICE OF ELECTION TO ADOPT STIPULATED PROTECTIVE ORDER

_____, a non-party to the above-captioned actions, has been requested and/or subpoenaed by a party to produce discovery containing CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION in connection with the above-captioned actions.

_____, hereby elects to adopt the terms of the Protective Order with regard to its terms regarding production of CONFIDENTIAL INFORMATION and HIGHLY CONFIDENTIAL INFORMATION.

The provisions of the Protective Order shall apply to all documents, things and other information produced by _____ as if such discovery were being provided by a party. _____ shall have the same rights and obligations under the Protective Order as held by the parties.

Dated: _____

Name

Company

Title